pivot MEDICAL

K110473

MAY 25 2011

Section 5. 510(k) Summary

510(k) Owner
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Date Summary Prepared: February 16, 2011

Device Name

Trade Name:	NanoTack Suture Anchor 1.4mm
Common Name:	Bone Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation number:	21 CFR888.3040
Product Code:	MBI

Predicate Devices
Smith and Nephew BioRaptor 2.3PK Suture Anchor – K071586

Biomet Sleeve with ZipLoop™ Fixation Device – K080088 and K101063

Device Description
The Pivot NanoTack Suture Anchor is a non-degradable suture anchor manufactured from PEEK-OPTIMA® polymer attached to a non-degradable ultra high molecular weight polyethylene (UHMWPE) blue co-braid #1 suture that is pre-assembled to a stainless steel Inserter. The NanoTack Suture Anchor with Inserter is provided as a single-use sterile device.

Intended Use
The NanoTack Suture Anchor is intended for the fixation of soft tissue to bone in the hip, and is indicated for the reattachment of hip labrum to the acetabulum.

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Summary of Technological Characteristics

The Pivot NanoTack Suture Anchor is substantially equivalent in design, materials, and function to the BioRaptor 2.3PK (K071586) and the Biomet Sleeve with ZipLoop (K080088 and K101063) predicate devices. The only difference between the NanoTack Suture Anchor and the BioRaptor 2.3PK is that the NanoTack utilizes a smaller size suture. The only difference between the NanoTack Suture Anchor and the Biomet Sleeve with ZipLoop is that the NanoTack anchor body is PEEK and the Biomet anchor body is polyester suture.

Summary of Performance Testing

The performance testing conducted demonstrates that the insertion and fixation properties of the NanoTack Suture Anchor are substantially equivalent to the Smith and Nephew BioRaptor 2.3PK and the Biomet Sleeve with ZipLoop anchors.

Summary of Substantial Equivalence

Based upon the indications for use, technological characteristics, and comparison to the predicate devices, the Pivot NanoTack Suture Anchor is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pivot Medical Inc.
% Mr. Jon Cook
Director Regulatory Affairs and Quality Assurance
247 Humboldt Court
Sunnyvale, California 94089

MAY 25 2011

Re: K110473
Trade/Device Name: NanoTack Suture Anchor 1.4mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 17, 2011
Received: May 19, 2011

Dear Mr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pivot Medical

Indications for Use

510(k) Number (if known): K110473

Device Name: NanoTack Suture Anchor

Indications for Use:

The NanoTack Suture Anchor is indicated for the reattachment of hip labrum to the acetabulum.

Prescription Use ___X___ AND / OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110473